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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,345	02/26/2007	Nobuaki Takahashi	081356-0262	3671

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EXAMINER	
GAMBEL, PHILLIP	

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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,345	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *137-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *137-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :06/23/2006, 06/15/2007, 12/11/2008, 08/14/2009.

DETAILED ACTION

1. Applicant's amendment filed 02/26/2007, has been entered.
Claims 1-94 have been canceled.
Claims 95-136 have been added.

Applicant's amendment filed 02/26/2007, has been entered.
Claims 1-136 have been canceled. Claims 1-94 have been canceled previously.
Claims 137-139 have been added.

Claims 137-139 are under consideration in the instant application.

2. The information disclosure statement filed 06/23/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The receipt of such copies is not indicated on the PCT/DO/EO/903 form in the file, burden is on the applicant to supply copies for consideration. See MPEP § 1893.03(g).

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Appropriate corrections are required.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The Brief Description of the Drawings is objected to, given the absence of the appropriate SEQ ID NOS. associated with the sequences described in the drawings. See 37 CFR 1.821(d) and MPEP 2422.03.

Appropriate corrections are required

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 137-139 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: See the recitation of Claim 137 as follows.

137. (New) An isolated monoclonal antibody that consists of two heavy chains, each consisting of an amino acid sequence ranging from Q at position 27 to K at position 474 of SEQ ID NO: 140, and two light chains, each consisting of an amino acid sequence ranging from A at position 23 to C at position 235 of SEQ ID NO: 142.

Applicant's amendment, filed 02/16/2009, provides the following support for the newly added claims as follows.

III. Support for the Claims

As discussed in greater detail below, the present claims are supported in the specification at page 35, line 5 - page 38, last full paragraph, and in Examples 15, 16, and 19. Thus, the antibody of the present claims has two heavy chains and two light chains, in keeping with "the fundamental structure of immunoglobulin" proteins, detailed in the specification at page 38, lines 17 and 18. Accordingly, the present amendment introduces no impermissible new matter.

While applicant directs written support for the newly added claims to the particular 4D11,

the written support for the particularities of the ranges and modifications recited in claim 137 on pages 35-38 and Examples 15, 16 and19 are not readily apparent in the specification as-filed.

For example, the written description of ranges per se as well the modifications of K at position 474 of SEQ ID NO: 140 from A at position 23 to C at position 235 of SEQ ID NO: 142 are not readily apparent in the specification as-filed.

The specification as filed does not provide a sufficient written description of the newly added claim 137. The specification does not provide sufficient blazemarks nor direction for the instant 4D11-based anti-CD40 antibody reciting the above-mentioned "limitations of claim 137", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations of claim 137" indicated above.

See MPEP 714.02 and 2163.06

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 137-139 are rejected under 35 U.S.C. § 103(a) as being unpatentable Mikayama et al. (WO 02/088186) (1449; filed 06/23/2006) as evidenced by Mikayama et al. EP 1391464 A1) (1449; #C5) in view of Erickson-Miller et al. (U.S. Patent No. 6,998,124), Taylor (U.S. Patent No. 6,936,698) and Holmes et al. (U.S. Patent No. 6,376,653).

Mikayama et al. (WO 02/088186) teach the 4D11 anti-CD40 antibody (e.g., see section (12) and Table on page 11; pages 23, 27, 28, 29, 38, 42, 51-53, and Claims)) as well as pharmaceutical compositions thereof as well as prophylactic and therapeutic methods to inhibit immunological graft rejection of GVHD (e.g., see Pharmaceutical Compositions on columns 15-17) (see entire document).

Given that Mikayama et al. (WO 02/088186) is in Japanese,
Mikayama et al. (EP 1391464 A1) is provided as evidence of the English equivalent Mikayama et al. (WO 02/088186) in view of Erickson-Miller et al. (U.S. Patent No. 6,998,124), Taylor (U.S. Patent No. 6,936,698) and Holmes et al. (U.S. Patent No. 6,376,653).

Mikayama et al. (EP 1391464 A1) teach the 4D11 anti-CD40 antibody (see pages 6, , 7, 10, 11, 14, 15, 16, 20, 21, 24, 34, 35; Brief Description of the Drawings on page 12; Claims)
as well as pharmaceutical compositions thereof as well as prophylactic and therapeutic methods to inhibit immunological graft rejection of GVHD (e.g., see Pharmaceutical Compositions on pages 11-12)

Mikayama et al. differs from the claimed invention by not explicitly teachings of modifying the base/reference 4D11 antibody of the claimed invention.

The following references provide for modifying therapeutic antibodies containing point mutations S228P and L235E in the IgG4 constant region at the time the invention was made.

Erickson-Miller et al. (see entire document, particularly column 11, paragraph 4) teach the following.

Preferably, the heterologous framework and constant regions are selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. IgG1, k and IgG4, k are preferred. Particularly preferred is IgG 4, k. Most particularly preferred is the IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function. This IgG4 subtype variant is known herein as IgG4PE. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

Holmes et al. (see entire document, particularly column 11, paragraph 4) teach the following.

Preferably, the heterologous framework and constant regions are selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. IgG1, k and IgG4, k are preferred. Particularly preferred is IgG 4, k. Most particularly preferred is the IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function. This IgG4 subtype variant is known herein as IgG4PE. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

Taylor (see entire document, particularly teach the following.

The engineered V regions are then joined to one or more different human or Old World ape constant regions depending on the desired secondary immune functions such as complement fixation or Fc receptor binding. Human constant regions can be selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. An IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function can also be selected. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

One of ordinary skill in the art at the time the invention was made would have been motivated to provide modified IgG4 immunoglobulin variants of the 4D11 anti-CD40 antibody, given the teachings of the prior art of providing IgG4 modifications to therapeutic antibodies of interest in order to increase half-life or to modify effector function of therapeutic antibodies, as taught by the secondary references. A person of ordinary skill in the art at the time the invention was made would have been motivated by taking the advantages of the providing such IgG4 modifications to therapeutic antibodies of interest with an expectation of success, since such properties and advantages are consistent with human therapeutic regimens associated with treating said conditions at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g., 4D11 antagonistic anti-CD40 antibody and known modifications to IgG4-based therapeutic antibodies to modify effector function and/or increase half-life) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (modifying therapeutic antibodies of interest) to target cells of interest in order to treat diseases of interest (e.g., antagonistic 4D11 antibodies and inhibiting graft rejection) with no change in their respective functions and the combination would have yielded nothing more than predictable results of providing therapeutic 4D11 antagonistic antibodies as well as their applicability in the inhibition of graft rejection.

The rationale to support a conclusion that the claims would have been obvious is that a method of decreasing effector function and/or increasing half-life via modifying IgG4-based therapeutic antibodies of interest was made part of ordinary capabilities of one skilled in the art based upon the teachings of the prior art. One of ordinary skill in the art would have been capable of applying the known recombinant methods of modifying IgG4-based therapeutic antibodies in order to increase the half-life and/or to modify effector function of therapeutic antibodies of interest to target cells and molecules of interest in various modalities, including the inhibition of graft rejection and would have been predictable to one of ordinary skill in the art at the time the invention was made.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (modifying IgG4-based therapeutic antibodies in order to increase half-life and/or to modify effector function) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying these known techniques to a known product (e.g., 4D11 anti-CD40 antibodies) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

The rationale to support a conclusion that the claim would have been obvious is that a person of ordinary skill has good reason to pursue the known options (e.g., modifying IgG4 therapeutic antibodies of interest to increase half-life and/or modify effector function) within his or her technical grasp. This leads to the anticipated success of modifying therapeutic antibodies such as the 4D11 anti-CD40 antibodies with increase half-life and/or modified effector function. It is likely the product not of innovation but of ordinary skill and common sense.

Since modifying IgG4-based therapeutic antibodies of interest would have been predictable at the time of the invention, there would have been reasonable expectation of successful development of a modified IgG4-based 4D11 antibody to increase half-life and/or to modify effector function. The prior art had recognized the advantages of modifying therapeutic antibodies to comprise modified IgG4-based antibodies to increase half-life and/or to modify effector function and had suggested and relied upon such modifications to accomplish this goal. The claims were obvious because it would have been obvious to try modifying the known 4D11 antibody as a modified IgG4-based

antibody to increase half-life and/or to modify effector function with a reasonable expectation of success.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to employ 4D11 antibodies as therapeutic agents, incorporating known IgG4-based modifications to therapeutic antibodies of interest to increase half-life and/or to modify effector function in the 4D11 anti-CD40 antibody would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic molecules with improved half-life and desirable functions.

8. Claims 137-139 are rejected under 35 U.S.C. § 103(a) as being unpatentable Mikayama et al. (U.S. Patent No. 7,193,064 (1449; #E1) in view of Erickson-Miller et al. (U.S. Patent No. 6,998,124), Taylor (U.S. Patent No. 6,936,698) and Holmes et al. (U.S. Patent No. 6,376,653).

Mikayama et al. teach the 4D11 anti-CD40 antibody (e.g., see Section (12) on column 8; Table on column 9; Sections (13)-(14) on column 9; Section (j) on column 15; Examples 2-4 on columns 18-22; Example 14 on columns 28-29; Example 17, particularly columns 43-44; Example 19 on columns 55-56; Figures 15 and 18 and 19, see Brief Description of the Drawings on column 17; and Claims) as well as pharmaceutical compositions thereof as well as prophylactic and therapeutic methods to inhibit immunological graft rejection of GVHD (e.g., see Pharmaceutical Compositions on columns 15-17)

Mikayama et al. differs from the claimed invention by not explicitly teachings of modifying the base/reference 4D11 antibody of the claimed invention, particularly as it read on the antibodies containing point mutations S228P and L235E in the IgG4 constant region (e.g., see Modification of Antagonistic Antibodies on pages Example 11 of the instant application)

The following references provide for modifying therapeutic antibodies containing point mutations S228P and L235E in the IgG4 constant region at the time the invention was made.

Erickson-Miller et al. (see entire document, particularly column 11, paragraph 4) teach the following.

Preferably, the heterologous framework and constant regions are selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. IgG1, k and IgG4, k are preferred. Particularly preferred is IgG 4, k. Most particularly preferred is the IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function. This IgG4 subtype variant is known herein as IgG4PE. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

Holmes et al. (see entire document, particularly column 11, paragraph 4) teach the following.

Preferably, the heterologous framework and constant regions are selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. IgG1, k and IgG4, k are preferred. Particularly preferred is IgG 4, k. Most particularly preferred is the IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function. This IgG4 subtype variant is known herein as IgG4PE. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

Taylor (see entire document, particularly teach the following.

The engineered V regions are then joined to one or more different human or Old World ape constant regions depending on the desired secondary immune functions such as complement fixation or Fc receptor binding. Human constant regions can be selected from human immunoglobulin classes and isotypes, such as IgG (subtypes 1 through 4), IgM, IgA, and IgE. An IgG4 subtype variant containing the mutations S228P and L235E (PE mutation) in the heavy chain constant region which results in reduced effector function can also be selected. See U.S. Pat. Nos. 5,624,821 and 5,648,260.

One of ordinary skill in the art at the time the invention was made would have been motivated to provide modified IgG4 immunoglobulin variants of the 4D11 anti-CD40 antibody, given the teachings of the prior art of providing IgG4 modifications to therapeutic antibodies of interest in order to increase half-life or to modify effector function of therapeutic antibodies, as taught by the secondary references. A person of ordinary skill in the art at the time the invention was made would have been motivated by taking the advantages of the providing such IgG4 modifications to therapeutic antibodies of interest with an expectation of success, since such properties and advantages are consistent with human therapeutic regimens associated with treating said conditions at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie

obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g., 4D11 antagonistic anti-CD40 antibody and known modifications to IgG4-based therapeutic antibodies to modify effector function and/or increase half-life) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (modifying therapeutic antibodies of interest) to target cells of interest in order to treat diseases of interest (e.g., antagonistic 4D11 antibodies and inhibiting graft rejection) with no change in their respective functions and the combination would have yielded nothing more than predictable results of providing therapeutic 4D11 antagonistic antibodies as well as their applicability in the inhibition of graft rejection.

The rationale to support a conclusion that the claims would have been obvious is that a method of decreasing effector function and/or increasing half-life via modifying IgG4-based therapeutic antibodies of interest was made part of ordinary capabilities of one skilled in the art based upon the teachings of the prior art. One of ordinary skill in the art would have been capable of applying the known recombinant methods of modifying IgG4-based therapeutic antibodies in order to increase the half-life and/or to modify effector function of therapeutic antibodies of interest to target cells and molecules of interest in various modalities, including the inhibition of graft rejection and would have been predictable to one of ordinary skill in the art at the time the invention was made.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (modifying IgG4-based therapeutic antibodies in order to increase half-life and/or to modify effector function) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying these known techniques to a known product (e.g., 4D11 anti-CD40 antibodies) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

The rationale to support a conclusion that the claim would have been obvious is that a person of ordinary skill has good reason to pursue the known options (e.g., modifying IgG4 therapeutic antibodies of interest to increase half-life and/or modify effector function) within his or her technical grasp. This leads to the anticipated success of modifying therapeutic antibodies such as the 4D11 anti-CD40 antibodies with increase half-life and/or modified effector function. It is likely the product not of innovation but of ordinary skill and common sense.

Since modifying IgG4-based therapeutic antibodies of interest would have been predictable at the time of the invention, there would have been reasonable expectation of successful development of a modified IgG4-based 4D11 antibody to increase half-life and/or to modify effector function. The prior art had recognized the advantages of modifying therapeutic antibodies to comprise modified IgG4-based antibodies to increase half-life and/or to modify effector function and had suggested and relied upon such modifications to accomplish this goal. The claims were obvious because it would have been obvious to try modifying the known 4D11 antibody as a modified IgG4-based antibody to increase half-life and/or to modify effector function with a reasonable expectation of success.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to employ 4D11 antibodies as therapeutic agents, incorporating known IgG4-based modifications to therapeutic antibodies of interest to increase half-life and/or to modify effector function in the 4D11 anti-CD40 antibody would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic molecules with improved half-life and desirable functions.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to provide antagonistic anti-PSGL-1 antibodies to treat a variety of inflammatory, autoimmune and cancer conditions, incorporating multimeric antagonistic anti-PSGL-1 antibodies in kits comprising said antibodies and instructions for use would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such kits for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 137-139 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of USSN 11/663,340.

Although the claims are not identical, the claims appear to be drawn to the same or nearly the same CD40-specific antibodies, comprising the same or nearly the same IgG4 modifications. In addition, the copending claims include compositions for the intended use of in the treatment of transplantation. The claims anticipate or render obvious one another.

11. Claims 137-139 are directed to an invention not patentably distinct from claims 1-7 of commonly assigned USSN 11/663,340 for the reasons set forth above in Section 10.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 11/663,340, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. No claim allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
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Art Unit 1644
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